

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

In Re:)	
)	
AREDIA and ZOMETA PRODUCTS)	No. 3:06-MDL-01760
LIABILITY LITIGATION)	Judge Campbell/Brown
(MDL No. 1760))	
)	
This Document Relates to: ALL CASES)	

O R D E R

A lengthy court hearing was held on all matters pending before the Magistrate Judge on January 22, 2007. The Magistrate Judge appreciates the efforts the parties put into resolving the various issues pending in this very complex case involving apparently over six million pages of discovery. The case is under a scheduling order which contemplates resolution of this litigation under the auspices of multi-district litigation as soon as practicable.

During the course of the proceedings so far, a number of issues have arisen. The parties have worked out a number of them on their own, but have requested Court assistance on certain issues that remain. The Plaintiffs filed a motion to compel (Docket Entry 230). That motion is **GRANTED** in part and **DENIED** in part as discussed below.

The Plaintiffs are asking for a great deal of information and the Defendant, on a rolling basis, is providing a great deal of information. As the Magistrate Judge understands it, we are somewhere, at the present time, in the range of six million pages. With this much material, differences will arise.

The Plaintiffs, in order to leave no stone unturned, have phrased their questions in broad, expansive terms. The Defendant, in responding, has in some cases, objected on the grounds of privilege, relevancy and other proper grounds. In other cases, the Defendant has simply provided massive studies and reports, advising the Plaintiffs that it is equally burdensome to Defendant as it is to the Plaintiffs to find the particular acorn of information that Plaintiffs seek. None of these procedures are necessarily bad. However, it does make it difficult for the Defendant furnishing the material, as well as for the Plaintiff receiving the material, to sort wheat from chaff. The Magistrate Judge continues to urge the parties to ask questions that are as sharply focused as possible and for the responding party to answer a sharply-focused question as completely as possible. Unfortunately, extremely broad questions tend to produce extremely broad objections and/or extremely broad responses which must then be sorted through by the other side and, at times, by the Court.

Those general remarks having been put forth, the Magistrate Judge will now turn to the specifics of the hearing and issues raised by the Plaintiffs in their motion to compel (Docket Entry 230) and Defendant's response thereto (Docket Entry 260).

1. **Redactions.** The first issue is redactions. The Plaintiffs argue that "tens of thousands" of responsive documents have been improperly blacked out without any explanation or notation in the privilege log. The Defendant has advised that it redacts information based on (1) privilege, (2) regulatory

requirements, and (3) relevance. The Defendant advises it has provided a complete privilege log identifying all documents redacted or withheld on the basis of privilege and further argues that no log of relevancy or privacy redaction is required under Federal Rules of Civil Procedure 26(b)(5).

Related to this issue is Issue 21, Designation of Documents As Confidential. The Plaintiffs assert, and the Defendant concedes, that every document produced by Defendant to date is marked as confidential pursuant to the protective order. Plaintiffs argue that this is an unnecessary burden which requires them to file everything under seal. The Defendant argues that the Plaintiffs should have brought this up long ago and that it is perfectly willing to meet with the Plaintiffs to remove this marking from any documents that the Plaintiffs request, unless there is a specific reason to retain it. The Defendant argues that given the volume of material and its efforts to provide the Plaintiffs with as much material as quickly as possible, it has only reviewed the material for privilege, confidentiality redactions and relevancy and, as mentioned above, has then designated everything as confidential. Defendant argues that it would be extremely burdensome to try to make the confidentiality designation at the same time as making the other designations.

The Magistrate Judge believes that the Defendants may not simply designate every document produced as confidential. The Plaintiffs have pointed out that the Defendant has used this blanket use of protective order to designate newspaper and magazine articles as confidential. Had this been raised with the Magistrate

Judge at an earlier time, he could have given earlier guidance. It appears to the Magistrate Judge that if Defendant is reviewing the documents for relevancy, privilege, and confidentiality redactions, it is not an undue burden for the Defendant to determine whether a produced document should be designated as confidential. The Defendant shall make reasonable efforts to designate as confidential only those documents which, in fact, it contends should be maintained as confidential under the protective order.

A more difficult situation is presented by those documents already so designated. The parties are under a tight schedule and to require the Defendant to go back at this point and re-examine the documents would likely delay production of future documents. Accordingly, the Magistrate Judge will not require the Defendant to redesignate those documents already provided. However, the Magistrate Judge expects the Defendant to promptly agree to remove the confidentiality designation from any documents presented by the Plaintiffs when it receives a reasonable request to remove the designation. If the Magistrate Judge believes that the Defendant withholds a change of designation or unduly designates documents as confidential, the Magistrate Judge will impose on the Defendant the Plaintiffs' costs in remedying the situation.

As to the redactions, while Rule 26(b)(5) does not expressly require a log to support the redactions, the Magistrate Judge believes that the Plaintiffs are entitled to some explanation as to why something is redacted. There is a big difference between a portion of the document being marked out as irrelevant and a

portion of the document being marked out as confidential. The Plaintiffs have no way of knowing whether the redaction is due to some claim of statutory or regulatory confidentiality or immateriality when it is simply blocked out without explanation. The Plaintiffs have contended that up to twenty percent (20%) of the material provided to them so far has material redacted without a claim of privilege, which apparently is being supported by a privilege log.

The Defendant may have eliminated a good bit of the dispute regarding redactions as it has advised that it is providing Plaintiffs with the new drug applications (NDA) in unredacted form. These documents apparently run to a million plus pages and the unredacted documents the Defendant has now agreed to provide may well alleviate much of Plaintiffs' concerns.

In short, the Magistrate Judge does not believe that the Defendant can universally designate everything as confidential and, at the same time, redact a portion of the material as confidential. If documents are designated as confidential, the Defendant does not need to withhold them as confidential unless there is, perhaps, a specific regulatory or statutory basis for doing so.

Given the volume of material, the Magistrate Judge expects that some material that perhaps should be confidential by regulation might slip through. In those cases, the parties do have provisions that would allow its return. The Magistrate Judge trusts that the parties will fully comply with the spirit of such provisions.

2. **Objections to Interrogatories.** The Defendants have provided a numbered list of general objections and in response to particular interrogatories have then referred by item number to these general objections as they apply to each interrogatory. So long as the Defendant is designating particular objections to each individual interrogatory, the use of this shorthand way makes sense to the Magistrate Judge. Otherwise, the responses would become unmanageably long. However, the Magistrate Judge does encourage the parties to keep objections to a minimum. If, in keeping with this exhortation, the Defendant is hit with a waiver argument, the Magistrate Judge will be sympathetic to its position that it did not intend to waive by failing to make every possible objection.

3. **Watermarks.** It appears that this item has been resolved between the parties with the exception as to which party should be responsible for the cost to reproduce the production of material without the watermark, which is approximately \$3,500. Rather than getting into a hair-splitting argument over who bears what part of this expense, the Magistrate Judge believes that the Defendant should bear this particular cost. If the Magistrate Judge had to get into a hair-splitting contest over it, he would be sympathetic to the Defendant's argument that the cost could have been reduced had the Plaintiffs raised this issue at a much earlier date. However, it appears the Plaintiffs will also incur costs to input and use the new material produced without the watermark. Therefore, each party should bear its own costs.

4. **Defendant's Initial Disclosure of "Core" and "Fifty" Employees.** The Plaintiffs argue that the Defendant has not fully

identified individuals having discoverable information in its initial disclosures as well as in its responses to Interrogatories 27 and 28. The Defendant claims that the Plaintiffs did not specifically request job titles, positions, or duties of those individuals before raising this issue with the Court. The Defendant indicated it is willing to give Plaintiffs the job titles, positions, and duties that are reasonably available. In view of this concession, the Defendant should provide this information as soon as possible. As far as employees who are no longer employed, the Defendant should provide the Plaintiffs with those individuals' last known addresses.

5. Identities of Non-Norvatis Employee Professionals.

The Plaintiffs argue that the Defendant has failed to provide the name of non-Norvatis professionals doing work in connection with the drugs. Plaintiffs contend that the Defendant has offered some, but not all, of these names, and then only if certain conditions are met. The Defendant responded that it has offered to give Plaintiffs unredacted copies of a list of names so Plaintiffs can identify the non-Norvatis employees. The Defendant seeks to condition this disclosure on the grounds that if any individual protected by 21 C.F.R. 20.63(f) is inadvertently revealed, Plaintiffs would immediately inform the Defendant and not use that information. Defendant further requests Plaintiffs inform Defendant before contacting any non-Norvatis employees.

The Magistrate Judge believes that the information requested, including the last known address of these non-Norvatis employees, should be furnished subject to inadvertent disclosure of

all persons protected by 21 C.F.R. 20.63(f). The issue of contact, if a non-Norvatis employee, is covered in the case management order and the parties should comply with that. The Magistrate Judge, at this point, does not see the need to modify that case management order regarding this contact.

6. **Interrogatory Answers.** The Plaintiffs argue that in "a number of instances" the Defendant answered interrogatories by referring Plaintiffs to its document production. The Defendant cites the Federal Rule of Civil Procedure 33(d) arguing that it has the option to produce business records if the response may be derived or ascertained from these business records and the burden of deriving or ascertaining the answer is substantially the same for the Plaintiffs as it is for Defendant.

Unfortunately, the devil is in the details for this type of material when the Plaintiffs ask for specific information, such as who conducted various tests. It is the Magistrate Judge's view that the Defendant must research its documents and answer Plaintiffs' specific questions. When the Plaintiffs ask broad questions, such as what was the outcome and procedure of any test or trial in the past two decades, Defendant is correct that by furnishing the test itself that information is equally available to both it and the Plaintiffs. The more specific the question is, the more the scale tips toward Defendant having to provide a specific answer. The more the questions tip toward broad and all encompassing, the more the burden tips to the Plaintiffs to sort out this information. In any case, however, the Defendant must

identify by Bates numbers specifically where this information is likely to be found.

7. Person Supervising the Testing of the Medications.

and 8. Interrogatory 12 - Testing Performed on the Drugs.

Defendant has advised that it is now providing the Plaintiffs with unredacted NDAs and that this information is contained in those reports, along with all drug testing performed in connection with the application for the new drugs. Again, where the Plaintiffs have asked for specific names of individuals connected with testing, the Defendant should provide a specific list of names. The Defendant, however, is not required to summarize the results of the various tests and studies. Summaries are equally available to either party.

9. Interrogatory 13 - Identities of Dentists/Oral Cavity Specialists Participating in Testing. The Plaintiffs assert that they have not been given an adequate answer to this interrogatory, having simply been referred to six million documents.

The Defendant responded that it has provided the NDA which contain the detailed information, including the identities of the study participants. Defendant also contends that it has provided the Plaintiffs with an index of Bates ranges for the NDAs to aid them in finding the study and trial reports. The Defendant has advised that it will recheck its records to see if it can determine what dentists and oral cavity specialists participated in testing within thirty (30) days. Defendant points out that there

is some difficulty in doing this because an individual with a medical degree may or may not also have a specialty as an oral or maxillofacial surgeon, periodontist, or endodontist, etc. However, this is an example where the Plaintiffs have asked a specific question rather than requesting a summary of years of study. Therefore, the Defendant must provide a specific answer.

10. Interrogatory 16 - Identity of Consultants Researching the Safety of the Drugs. The Magistrate Judge believes that inasmuch as the Defendant is now furnishing unredacted copies of the NDAs, that this material will be contained therein. This, in combination with the other references the Defendant has previously given, is a sufficient answer to this extremely broad question.

11. Interrogatory 19 - Studies Regarding Causal Connection to ONJ. The Magistrate Judge was advised at the hearing that the parties had resolved this issue.

12. Interrogatory 26 - Other Lawsuits Concerning the Drugs. The Plaintiffs have requested the case styles and attorneys regarding other lawsuits involving the drugs in this action. The Defendant has stated it need not respond because the lawsuits are not relevant under Federal Rules of Civil Procedure 26(b)(1).

The Magistrate Judge is of the opinion that Defendant should provide the Plaintiffs with the names and identifying data of any cases filed against Defendant or its subsidiaries which involve the subject matter of the present MDL litigation. The Defendant does not have to provide information on lawsuits

unrelated to this subject matter, such as Title 7 violations, or other drug cases not related to the two drugs in this litigation. The Magistrate Judge believes that the Defendant does need to provide information about suits pending against its subsidiaries, as this information should be in its control.

13. Document Request 10 - Correspondence Relating to the Drugs. The Plaintiffs argue that the Defendant states that it does not correspond with foreign agencies. Plaintiffs are concerned that this may mean that sister or parent companies related to Defendant correspond with foreign companies on its behalf regarding foreign adverse events. The Defendant points out that it does have to provide adverse event reports to the FDA regardless of where they occur or who discovered them. Defendant states that it has provided these reports and will continue to do so.

The Magistrate Judge believes that this is sufficient. Certainly, if the Defendant has these reports they must be provided to Plaintiff. Further, if Defendant has correspondence related to those reports, such correspondence should also be provided unless otherwise privileged.

14. Document Requests 35 and 36 - Norvatis Sales and Profits. The Plaintiffs have requested sales and profit information from Defendant, particularly such information regarding the two drugs at issue. The Plaintiffs stated that this information would be useful to determine not only potential for punitive damages, but also to determine the amount of sales of these two drugs. They contend this would be relevant on their claim for class certification. The Magistrate Judge believes this

request is premature and need not be answered at the present time. Insofar as this information relates to potential punitive damages, the case at the present time has not progressed to a point where it is apparent that punitive damages would be considered. To the extent the Plaintiffs need this information to determine the amount of sales, it appears that this information can be asked for more directly without getting into the Defendant's profit and loss statements and other financial data.

15. **Index of Documents Being Produced.** During the discussion of this matter, it appears that the parties have resolved this issue.

16. **Information Required to Search Documents.** The Plaintiffs argue that the Defendant has produced images and emails and other electronic documents in a way that severely restricts the useability and retrievability of the information. In particular, Plaintiffs contend that the material does not include the date sent, date received, author/sender, recipients and/or title of document/email subject. The Defendant responded that the Plaintiffs should have raised this issue months ago if they had a problem because now millions of pages have already been produced. Defendant pointed out that the parties had an agreed protocol that the Defendant would produce images of all hard copy and electronic documents in .TIF format along with OCR or extracted text files for most documents in accordance with the case management order.

The Magistrate Judge agrees with the Defendant on this point. It appears that the Defendant has complied with the agreed protocol the parties worked out concerning this production. It

appears that the Plaintiffs now wish to have additional material provided and that this can be done relatively easily. To the extent this is true, the parties may certainly agree to have additional search fields provided for documents produced in the future. However, the Magistrate Judge will not require the Defendant at their expense to go back and redo documents which were produced in accordance with the agreed protocol. If the Plaintiffs believe that it is necessary to have documents reproduced with this data on it, any such reproduction will have to be at the Plaintiffs' cost.

The Magistrate Judge would suggest that the parties' technical experts confer on any change to the protocol and would further suggest that the protocol be amended where it can be done at minimal cost for future productions.

17. Missing Items in Production. To the extent material is missing information such as Bates numbers, identifying information, OCR, or extracted text information, the Defendant should promptly correct any such deficiencies that are called to its attention.

18. Anderson Clinic Study Data. There is an ongoing study by the Anderson Clinic which has not yet been published. The Defendant has been providing supplements to the Plaintiffs as it has received such information and have advised that it will continue to do so. Defendant points out, however, that the Anderson Clinic has not published this study, and therefore, a final report is not available at this time.

19. Completion Date for Document Production. The Plaintiffs point out that while they are grateful for the rolling discovery they are receiving, there are deadlines approaching. Plaintiffs are concerned that some sort of overall deadline for completion of discovery is needed. The Defendant does not necessarily object to this. However, the Defendant contends that the parties have not yet fully discussed the matter.

The parties advise that they may extend the deadlines for some depositions by agreement. So long as the extensions do not affect motion and hearing dates set in the scheduling order, the Magistrate Judge has no objection to the parties extending certain discovery dates. Additionally, the parties are directed to confer and recommend discovery completion dates for the Magistrate Judge, preferably by an agreed order. If the parties are unable to agree, they should submit, within the next ten (10) days, their separate proposals and the Magistrate Judge will fix completion dates as needed.

20. Proffer of Witnesses at 30(b)(6) Depositions. The Plaintiffs have complained about two witnesses being unprepared for their 30(b)(6) depositions. However, the Plaintiffs have now advised that the most recent 30(b)(6) deposition went smoothly. It appears that at the present time there is no need for the Magistrate Judge to deal with this issue. The Plaintiffs are encouraged to define as narrowly as possible the issues they wish a 30(b)(6) witness to cover. Where they do so, the Magistrate Judge fully expects the Defendant to provide a witness able to cover those issues. The problems come when the designations become

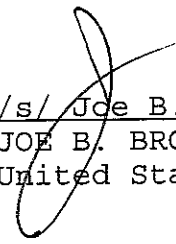
broad. However, from the hearing, it appears that the parties have resolved these issues. A discussion between the parties prior to the actual taking of the deposition can often narrow and clarify the expected scope of the 30(b)(6) deposition.

21. **Designation of Documents as Confidential.** This issue was dealt with at **Item 1** in this order.

22. **Plaintiff's Interrogatories.** The Plaintiffs have requested an additional twenty-five (25) interrogatories from the Defendant. The Defendant initially objected stating that this request had not been raised earlier and was only done so at the last minute. After discussion with the parties, the Plaintiffs may have an additional twenty-five (25) interrogatories.

A telephone conference call to discuss case progress, started by the Plaintiffs, is set for **March 6, 2007, at 1:30 p.m.**, unless the parties notify the Magistrate Judge that the telephone conference is unneeded.

It is so **ORDERED**.



JOE B. BROWN
United States Magistrate Judge